United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Date Program

SOP No.: PDP-ADMIN-06A		Page 1 of 7
Title: USDA/AMS Quality Assurance Program		
Revision: 8	Replaces: 04/15/-5	Effective: 04/01/07

1. Purpose:

To establish requirements and procedures for the USDA/AMS Pesticide Data Program (PDP) quality assurance program.

2. Scope:

This standard operating procedure (SOP) shall be followed by the USDA/AMS Monitoring Programs Office (MPO), Manassas, VA.

3. Outline of Procedure:

5.1 Overview
5.2 Files and Records
5.3 Method Validation
5.4 Proficiency Testing (PT) Program
5.5 Technical Advisory Group
5.6 SOPs and Deviations from SOPs

4. References:

- PDP QA/Technical Meeting, May 7-9, 2003
- QA Committee Meeting, May 19-21, 1998
- QA Committee Meeting, July 9-11, 1996
- USDA/AMS, EPA/OPP, EPA/OCM Meeting, Minutes, May 21, 1992
- Jon McNeal, Branch Chief, USDA/AMS Technical Services, Communication to William Franks, Jr., May 8, 1991
- U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, August 17, 1989

5. Specific Procedures:

5.1 Overview

5.1.a USDA/AMS shall ensure that a quality assurance (QA) program is in place to monitor overall QA for sampling, technical, and database functions. The Technical Director shall have overall responsibility for assuring USDA/AMS management that facilities, equipment, personnel, methods, practices, records, and controls of the program are in conformance with the plans and SOPs issued by USDA/AMS and all applicable Good Laboratory Practices (GLP) regulations.

5.1.b Specific QA functions shall be assigned by the Technical Director, in consultation with the Program Administrative Director, to appropriate sampling, technical, and database staff.

5.1.c Appropriate PDP residue records shall be maintained. Documents shall be maintained in a secure manner with reasonable environmental protection from deterioration for the life of the program. Electronic and hardcopy records shall be centrally maintained (i.e., on the shared drive and/or in the QA Records Room) according to established MPO procedures. Maintenance shall be in an organized and systematic manner which allows accessibility by authorized staff.

5.1.d The Technical Director, in consultation with the Administrative Director, shall appoint an individual to serve as the PDP Document Control Officer. The Document Control Officer shall serve as the focal point for selected documents, reports, and correspondence pertaining to program quality control (QC) and/or quality assurance (QA) issues.

5.2 Files and Records

5.2.a The Technical Director shall ensure that copies of the following documents are maintained in the centralized files:

> **5.2.a.1** PDP annual, semi-annual, or quarterly plans including the schedule of samples, chemicals, and commodities to be tested.
>
> **5.2.a.2** Schedule of USDA/AMS sampling and laboratory reviews and report submissions. This shall include the dates reviews were made and the dates findings were reported to appropriate individuals.

5.2.a.3 Special project status reports [e.g., supercritical fluid extraction (SFE), MS/MS] prepared by USDA/AMS chemists.

5.2.b The following documents are maintained in the centralized files by the assigned sampling or laboratory liaison(s):

5.2.b.1 Authorizations for deviations from the USDA/AMS SOPs.

5.2.b.2 Semi-annual internal laboratory QA status and yearly audit reports

5.2.b.3 Sampling and laboratory review reports.

5.2.c The following documents are maintained in the centralized files by the Document Control Officer:

5.2.c.1 Laboratory validation/evaluation data review reports and letters of concurrence/requests for additional data.

5.2.c.2 USDA/AMS SOPs, including administrative, sampling, laboratory, and USDA/AMS internal SOPs.

5.3 Method Validation

All laboratories are required to perform method validation studies according to SOP PDP-QC-07. Studies shall be submitted to the Technical Director for review and concurrence.

5.3.a The Technical Director is responsible for assigning primary review of the validation study to a liaison chemist. The liaison chemist reviews the study according to established internal procedures and drafts a letter of concurrence including any recommendations or requirements for additional data.

5.3.b A second MPO chemist performs an additional review of the data and makes recommendations based on findings.

5.3.c The Document Control Officer performs a final review of all validation/evaluation study reports prepared by liaison chemists to ensure that consistent policies are applied, makes recommendations based on findings, and:

5.3.c.1 Tracks and files all validation/evaluations study reports to ensure that all required studies are performed by all applicable laboratories and that letters of concurrence/requests for further data are issued by MPO in a timely fashion.

5.3.c.2 Promptly communicates to the Technical Director delays in study reports submission or issuance of MPO letters of concurrence/requests for further data.

5.3.d The Technical Director is responsible for final authorization of the letter of concurrence issued to the submitting laboratory.

5.4 Proficiency Testing (PT) Program

The Technical Director is responsible for management of the proficiency testing (PT) program. A PT schedule will be included in the PDP semi-annual program plans.

5.4.a All PDP laboratories analyzing fruit and vegetables, grains, and animal tissues, using either multi-residue or single analyte methods shall participate in proficiency testing programs as required by MPO. This may include international programs as specified by MPO.

5.4.b All PDP laboratories analyzing water (raw or finished drinking water or bottled water) will participate in PT sets designed by MPO and administered by a selected commercial vendor.

5.4.c The Technical Director shall ensure that PT samples are delivered on schedule and reports are prepared in a timely fashion and distributed to appropriate individuals. Distribution shall include the Program Administrative Director, MPO staff, and participating laboratory Technical Program Managers and QAUs.

5.4.d The Technical Director shall be responsible for overall monitoring of the proficiency of PDP laboratories.

5.5 Technical Advisory Group

5.5.a The USDA/AMS Technical Director shall serve as liaison to the USDA/AMS Technical Advisory Group (TAG). The committee shall be comprised of three selected members of participant QAOs or Technical Program Managers and shall address program QA issues/concerns.

5.5.b Each Committee member shall serve a three-year term, with the final year served as the Presiding Member. The Presiding Member shall have sign-off responsibility for USDA/AMS program SOPs, with the exception of administrative SOPs, developed or revised during their term.

5.6 SOPs and Deviations from SOPs

5.6.a The PDP Sampling Manager is responsible for preparing/revising all program sampling SOPs.

5.6.b The PDP Document Control Officer is responsible for preparing/revising all program laboratory SOPs. In addition, the Document Control Officer is responsible for preparing/revising PDP administrative procedures, in consultation with the Program Administrative Director and Technical Director.

5.6.c The Technical Director is responsible for ensuring that internal SOPs are prepared/revised.

5.6.d The Document Control Officer is responsible for maintaining all current and historical (archived) USDA/AMS SOP hardcopy and electronic files according to established MPO procedures. Refer to PDP-ADMIN-07, section 5.3, for specific details.

5.6.e The Technical Director shall ensure that any authorization for deviations from approved program plans or USDA/AMS PDP SOPs does not compromise integrity of data. The Technical Director shall ensure that precise and technically accurate documentation of such errors/deviations is maintained.

SOP No.: PDP-ADMIN-06A		Page 6 of 7
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- Modified format to conform with other SOPs

Revision 7

- Modified format to conform with other SOPs
- Updated to conform with current Monitoring Programs Office organization